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Applicant:	Bannon, et al.	Examiner:	Huynh, P.
Serial No.:	09/478,668	Art Unit:	1644
Filed:	January 6, 2000		
For:	METHODS AND REAGENTS FOR DECREASING CLINICAL REACTIONS TO ALLERGY		

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REPLY BRIEF UNDER 37 C.F.R. § 1.193

Appellant offers the present comments in Response to the Examiner's remarks in the Answer mailed October 21, 2004. Most of the Examiner's remarks in this Answer were restatements of previously-articulated positions, but some points were new; if a given item is not specifically discussed herein, then the Examiner has not presented new points of argument and/or Appellant relies on the arguments made in the Appeal Brief.

For ease of presentation, Appellant's comments in this Reply Brief are organized according to the headings and numbered issues presented in Appellant's Second Amended Brief submitted July 29, 2004 (the "Brief"). For the convenience of the Board, references to pages within the Examiner Answer are also included.

The deadline for filing a Reply Brief is December 21, 2004. Applicant thus submits that the present Reply Brief is timely filed on December 16, 2004.

Grouping of Claims

The Examiner states that Groups A, B, and C should stand and fall together both for purposes of issue 1 (enablement) and for purposes of issue 2 (written description) solely because "claims 65-71 are in Groups A, B, and C" (page 3 of the Examiner's Answer). Claims 65-71 are *multiply dependent* claims. The Brief clearly sets out that claims 65-71 are only included in Group A, B or C *to the extent that* they depend from base claims 37 (Group A), 60 (Group B) or 63 (Group C), respectively.

The Examiner is rigorously correct that these claims are present in all three Groups but, of course, this point is irrelevant. Different portions of the claims are present in each Group. The scope and content of the portions that are present in each Group differ and, for all of the reasons set forth in the Brief, the portions should stand or fall separately.

Argument

ISSUE 1: ***Claims 37-51, 53 and 60-71 are not Invalid for Lack of Enablement***

(A) In her Answer, the Examiner denies that she had previously acknowledged that the subject matter of Groups B (modified food allergens) and C (modified peanut allergens) was enabled. Specifically, the Examiner states (Page 20 of the Answer) that the only concession made was with respect to the modified peanut allergens shown in Tables 4-6 of the specification. The Examiner is mistaken. The Office Action mailed September 30, 2002 (Paper 24) includes a list of twenty embodiments that the Examiner explicitly conceded were enabled (see pages 2-4 of the Office Action). Item (1) refers to modified *peanut* allergens (Group C); item (16) refers to modified *food* allergens (Group B). In the Answer, the Examiner attempts to articulate a new legal standard (see point (B) below) under which these claims would not have been enabled. This new strategy does not negate her previous acknowledgement of enablement.

(B) As indicated above, the Examiner articulates a breathtaking new enablement standard in the Answer. According to this Examiner, it is not possible to enable a claim to a genus of proteins unless the complete amino acid sequence of every protein that falls within the scope of the claim is explicitly set forth in the application. Specifically, on several occasions in the Answer, the Examiner makes the following two statements:

> "Without the amino acid structure [sic] of *all* the modified protein allergen [sic] and modified food allergen [sic], one skill [sic] cannot make, much less use the modified protein allergen [sic] or modified food allergen [sic]" (*emphasis* added, see page 25).
>
> "Until the amino acid critical to IgE binding within the at least one IgE epitope essential for IgE antibody binding or within the full length polypeptide in *all* protein allergen [sic], *all* food allergen [sic] and *all* peanut allergen [sic] other than Ara h 1, 2 and 3 have been identified and the corresponding amino acids to be substituted in said at least one IgE epitope has [sic] been described, it would require undue amount of experimentation for one of skill in the art to arrive at the scope of the claimed invention" (*emphasis* added, see page 9, 23, 26, 34).

Applicant respectfully submits that the legal standard put forth by the Examiner in these remarks bears no relationship whatsoever to the standard that has been set forth in *Wands*, or in any other case. *Wands*, like all other enablement decisions, holds that a claim is enabled so long as no *undue experimentation* is required to practice the claimed invention to the scope of the claim. By contrast, this Examiner says that a claim cannot be enabled unless *absolutely no* experimentation is required. This is not, and should not be, the standard.

ISSUE 2: ***Claims 37-51, 53 and 60-71 are not Invalid for Lack of Written Description***

The Examiner adopts the exact same standard for written description as she does for enablement. Specifically, she states:

> "Until the amino acid critical to IgE binding within the at least one IgE epitope essential for IgE antibody binding or within the full length polypeptide in *all* modified protein allergen, *all* modified food allergen and *all* peanut allergen other than Ara h 1, 2 and 3 have been identified and the corresponding amino acids to be substituted in said at least one IgE epitope has been described, the modified protein allergen, and the modified food allergen obtained from a source selected from the group consisting of legumes other than peanut, milks, grains, eggs, fish, crustaceans and mollusks, wheat, barley, cow milk, egg, codfish, hazel nut, soybean, and shrimp are not adequately described" (*emphasis* added, see page 12, 39, 42, 44, 46).

As with enablement, it is apparently the Examiner's position that the written description requirement can never be satisfied for a nucleic acid or protein unless the complete sequence is explicitly set forth in the specification and recited in the claim by way of a SEQ ID NO. The absurdity of the Examiner's position is further emphasized by another statement that is repeated on several occasions throughout the Answer:

> "Even if the modified peanut allergen is limited to Ara h 1, Ara h 2 and Ara h 3 (claim 64), there is insufficient written description about the structure of said modified allergens without reciting the amino acid sequence in the claim" (*emphasis* added, see page 13, 39, 42).

This is clearly not the law nor should it be. The proper legal question is not "did Appellant *reduce to practice* and *explicitly recite* every modified peanut allergen that falls within the scope of the claims?" Instead, the question is "would a skilled person recognize that Appellant was in *possession* of the modified peanut allergens that fall within the scope of the claims?" As set out in the Brief it is Appellant's position that a skilled person would readily recognize that Appellant was in possession of the full scope of the claims.

ISSUE 4: ***Claims 37, 60 and 63 are not Indefinite for Reciting the Term "Substantially"***

On page 48, the Examiner maintains her objection to Appellant's use of the term "substantially". Without providing any reasoning the Examiner states that the term is unclear since a modified protein allergen having 50% sequence identity to an unmodified protein allergen would still be "substantially identical" to the unmodified protein allergen.

Appellant respectfully points out that those of ordinary skill in the art are expected to read and understand the term "substantially identical" in context, and can evaluate when a sequence will qualify as being substantially identical when it is 50% different, and when it will not. Appellant further points out, as argued in the Brief, that the courts have clearly stated that terms such as "substantially" may be used in patent claims when warranted by the nature of invention, in order to accommodate the minor variations that may be appropriate to secure the invention. *Verve LLC v. Crane Cams*, 311 F.3d 1116 (Fed. Cir. 2002). Appellant relies on the Brief for further explication of this position.

ISSUE 6: ***Claims 37, 60-61 and 63-71 are not anticipated by Burks (1997)***

On page 51, the Examiner argues again that this rejection under 35 U.S.C. § 102(a) is proper. Appellant respectfully disagrees – it is an axiom of patent law that a prior art reference cannot be used to anticipate an invention if the teachings of that prior art reference were included in the patent application or the patent application properly claims priority to such an application. As noted in the Brief, the teachings of Burks (1997) were included near *verbatim* in U.S. Serial

No. 08/717,933 filed September 23, 1996 (see pp. 133-155 and the Figures referred to therein). The present application properly claims priority to this 1996 filing. Burks (1997) was published after this priority date and cannot therefore be used as prior art under 35 U.S.C. § 102(a). Withdrawal of the rejection is earnestly requested.

Conclusion

For all of these reasons, Appellant respectfully submits that the pending claims are fully supported by the specification as filed and allowable over the art of record. The Examiner's rejections should be reversed.

Respectfully submitted,

December 16, 2004

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